DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 27, 2015

Shaser Incorporated
Mr. Anthony Burns
Senior Director of Regulatory Affairs
10 Maguire Road
Lexington, Massachusetts 02421

Re: K150282
Trade/Device Name: Shaser Skin Beauty Intense Pulsed Light System Family for Acne
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: April 30, 2015
Received: May 4, 2015

Dear Mr. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150282

Device Name
Shaser Skin Beauty Intense Pulsed Light System Family for Acne

Indications for Use *(Describe)*
The Shaser Skin Beauty Intense Pulsed Light System Family for Acne is an over-the-counter home use device intended to provide phototherapeutic light to the body, specifically indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

Submitter:	Shaser, Inc. 10 Maguire Road Lexington, MA 02421
Contact:	Anthony Burns Senior Director of Regulatory Affairs
Date Summary Prepared:	January 30, 2015
Device Trade Name:	Shaser Skin Beauty Intense Pulsed Light System Family For Acne
Common Name:	Light Based Acne Clearing Device
Classification Name:	Powered Light Based Non-Laser Surgical Instrument with Thermal Effect 79-ONF, 21 CFR 878.4810
Equivalent Devices:	Shaser Skin Beauty Intense Pulsed Light System Family (K141583) CLRS Technology Corp. CLARO (K090744)
Device Description:	Shaser Skin Beauty Intense Pulsed Light System Family For Acne is an Over-The-Counter, Light-Based Acne Clearing Device. Emission activation is by finger switch. Device includes a limited life treatment head and battery charger/AC cord. Electrical requirement is 115 VAC, 15A, 50-60 Hz, single phase. The Principle of Operation is both photochemical and photothermal. The Mechanism of Action is to stimulate oxygen production which attacks p.acne and to reduce inflammation due to acne.
Intended Use:	Treatment of Acne.
Indications For Use:	The Shaser Skin Beauty Intense Pulsed Light System Family for Acne is an over-the-counter home use device intended to provide phototherapeutic light to the body. It is also indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.
Comparison:	The Shaser Skin Beauty Intense Pulsed Light System Family For Acne has the same principle of operation and light source, and very similar wavelength range and pulse energy as the predicate devices. The proposed device has the same Intended Use as the CLARO predicate device.
Nonclinical Performance Data:	Bench testing for performance verification and electrical safety testing.

Clinical Performance Data:	Label comprehension and usability test of consumers' ability to understand the instructions for use and to evaluate their ability to use the device safely in a simulated home-use environment. • 84 study subjects were tested for label comprehension and for usability. The test populations included low literacy subjects. The results of the two tests confirms sufficient label comprehension and safe and appropriate use of the device.
Conclusion:	The Shaser Skin Beauty Intense Pulsed Light System Family For Acne is a safe and effective device for the intended use.
Additional Information:	None

TABLE OF COMPARATIVE FEATURES

	Proposed 510(k) Device	Predicate Device 510(k) K090744	Predicate Device 510(k) K141583
Manufacturer	Shaser, Inc.	CLRS Technology Corp.	Shaser, Inc.
Trade Name	Shaser Skin Beauty Intense Pulsed Light System Family for Acne	CLARO	Shaser Skin Beauty Intense Pulsed Light System Family
Intended Use	Acne Clearing Device	Acne Clearing Device	Removal of Unwanted Hair
Indications	The Shaser Skin Beauty Intense Pulsed Light System Family for Acne is an over-the-counter home use device intended to provide phototherapeutic light to the body, specifically indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.	The CLARO is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.	The Shaser Skin Beauty Intense Pulsed Light System Family is an over-the-counter home use device intended to provide phototherapeutic light to the body. It is also intended for removal of unwanted hair by using a selective photothermal treatment. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I – IV. The Shaser Skin Beauty Intense Pulsed Light System Family is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.
'Use' Classification	OTC	OTC	OTC
Device Classification	Class II	Class II	Class II
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light

TABLE OF COMPARATIVE FEATURES

	Proposed 510(k) Device	Predicate Device 510(k) K090744	Predicate Device 510(k) K141583
Wavelength (nm)	400 – 1100nm	400 – 1100nm	400 – 1200nm
Max. Fluence (J/cm^2)	6.0	6.0	10
Spot Size (cm^2)	2.0	1.0	2.0
Pulse Width (s)	6	6	<.2
Source Energy	AC Mains/Battery	Battery	AC Mains/Battery
User Interface	LCD display with text and graphics /LED Indicator lights	LED Indicator lights	LCD display with text and graphics /LED Indicator lights
Control Mechanism	Microprocessor based	Non-Microprocessor based	Microprocessor based
Treatment Regime	1 application = 6 seconds	1 application = 6 seconds	1 application < .2 seconds
	1 Treatment = 2 applications	1 Treatment = 2 applications	1 Treatment = 1 application
	No more treatments than: 1 every 8 hours 4 in a seven day period.	No more treatments than: 1 every 8 hours 4 in a seven day period.	No more treatments than: 1 every two weeks.